

Research article

Comparison between biofeedback Acapella and biofeedback flutter devices in COPD: A new way to improve airway clearanceAneesha Dhanraj Menezes^{1,2}, K. Rekha¹, B. Sanjeev Rai²¹Saveetha College of Physiotherapy, Saveetha Institute of Medical and Technical Sciences, Chennai, Tamil Nadu, India²Father Muller Research Centre, Mangalore, Karnataka, India

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ABSTRACT

Introduction and Aim: In recent years, biofeedback systems have been integrated into a variety of devices. Biofeedback system is the process of gaining awareness of one's physiological functions by an apparatus which provides participants feedback of their performance. Respiratory training with a biofeedback system provides the correct breathing pattern, reduces respiratory rate and tension, enhances respiratory function, improves gaseous exchange, improves ventilation and perfusion mismatch. Therefore, it reduces sympathetic nervous system activity by clearing secretions. As clearing the mucous from the airways is the initial stage of respiratory rehabilitation, this study sought to implement a biofeedback system in an Acapella and flutter device and compared the effectiveness of both the positive expiratory pressure (PEP) devices (Acapella and Flutter) with biofeedback on lung functions in chronic obstructive pulmonary disease (COPD) patients.

Materials and Methods: 30 patients were assigned randomly to the acapella group or the flutter group with 15 patients in each group. The Acapella biofeedback group used the Biofeedback Acapella device for 15-20 minutes per day for five days, while the Flutter biofeedback group used the Biofeedback Flutter device simultaneously.

Results: The biofeedback acapella group and the biofeedback flutter group showed significantly higher increases in forced vital capacity (FVC), forced expiratory volume in one second (FEV1), and oxygen saturation (SpO2). There was no significant difference between the groups. In addition, there was a significant difference in sputum weight, within both the groups reducing significant amounts of sputum and improving symptoms.

Conclusion: These results suggest that both Biofeedback Acapella device and the Biofeedback Flutter device help in improving lung function and oxygen saturation in COPD patients. Further scientific studies are needed to be performed to confirm the results and to determine the optimal durations and frequencies used in these devices. We also recommend further improvement and development of airway clearance devices.

Keywords: Chronic Obstructive Pulmonary Disease; COPD; Acapella; Flutter Biofeedback; forced vital capacity; Forced expiratory volume; Oxygen saturation; Sputum weight.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) describes respiratory system abnormalities typically caused by prolonged exposure to hazardous particles or gases. These abnormalities result in persistent respiratory symptoms and airflow limitation (1,2). Airway inflammation, mucociliary dysfunction, and the resulting airway structure are all factors in chronic obstructive pulmonary disease pathophysiology. In general, the lungs' airways are damaged and produce huge amounts of mucus. The excessive mucus causes airways to become inflamed, narrowed and blocked, leading to breathing difficulties (3).

COPD is a leading cause of mortality and morbidity worldwide. In 2016, three of India's top five causes of death were non-communicable diseases, while COPD is now the second most important reason of death in India (4). The widespread habit of tobacco smoking and other environmental pollutants has led to a high

prevalence of chronic obstructive pulmonary disease (5).

COPD includes chronic bronchitis and emphysema. Chronic bronchitis causes coughing up sputum most days for at least three months and two years in a row. Hypertrophy of mucous gland tissue in the trachea, bronchi, and bronchioles is characteristic of chronic bronchitis. The number of goblet cells increases, especially in the bronchioles. Hypertrophy of the mucous glands is accompanied by thickening of the mucosa and excessive mucus secretion, as well as hypertrophy of the bronchial wall muscles. Inadequate clearance of inhaled particles and infection of mucus in the tracheobronchial tree results in retention of sputum and increasing airway obstruction (6).

Destruction of airway bronchiolar walls which are caused due to inflammation, edema and thickened bronchiolar walls characterize emphysema. This damage is associated with prolonged smoking years, chronic cough which causes irreversible lung damage (7). Emphysema leads to airway obstruction due to the

loss of elastic restoring properties of the lungs. Chronic airway obstruction is characterized by wheezing and shortness of breath with or without a productive cough. Many patients with sputum production have mild wheezing between exacerbations, with sputum production typically occurring in the early morning.

Acapella is an airway clearance device which combines resistance properties of a positive expiratory pressure device with oscillation, which reduces mucus adhesion and decreases airway collapsibility. This allows the device to clear the airway more effectively (8), sending pulses of oscillation into the lung parenchyma that shakes the mucus plugs and helps patients to cough. This makes coughing more effective and forces secretions out of the body (9). Using a counterbalanced lever and magnet, the Acapella (DHD Healthcare, Wampsville, New York) integrates the principles of high-frequency oscillation and PEP. The exhaled air flows through a conical system that is obstructed intermittently by a stopper attached to a lever, creating an oscillating airflow. A knob at the distal end of the device regulates the distance between the magnet and the counterweighted socket, changing the frequency, amplitude, and mean pressure. The Acapella comes in two colors: a green device for patients who can maintain an expiratory flow of 15 L/min for at least three seconds and a blue device for patients who can maintain a flow of 15 L/min (10)

The Flutter device works on the principle of combining positive expiratory pressure therapy with high-frequency oscillations within the airways. During expiration, a controlled vibration system produces positive expiratory pressure and cyclic oscillations of the trachea. The Flutter is a small and portable device which helps patients with various respiratory diseases in removing mucus. The device consists of a tube in which a steel ball oscillates through a tubular device during exhalation. When one exhales into the flutter valve causes a steel ball-bearing oscillating at a high frequency, expelling mucus. Exhalation also causes expiratory pressure oscillations, which vibrates the walls of the airways, thereby, loosening the mucus and reduces the collapsing ability of the airways, accelerating airflow, facilitating the mucus movement within the airways, and improving lung functions and oxygenation (11). The Flutter and Acapella create positive expiratory pressure and oscillations through an obturator that acts with a measured force. This resistance to flow enables the generation of positive pressure. The Flutter exploits the attractive force of gravity. The Acapella utilizes the force of magnetic attraction (12).

Biofeedback (B.F.) is a method of controlling distinctive physiological functions, by using various instruments and artificial intelligence that provide information (such as electromyography, skin temperature, heart rate, blood pressure, and brain

waves) about the activities performed by these systems. Biofeedback has been shown to be effective in treating headaches and migraines when the instrument is used in conjunction with mental and physical activity (13). In this study, we used a basic and simple form of biofeedback to assess a patient's airway. A manometer is connected to an airway clearance device to provide visual feedback to the patient about the pressure exerted during exhalation. Breathing training with a visual feedback system facilitates proper breathing patterns that improve respiratory function, reduce respiratory rate and tension, improve gas exchange, improve ventilation and perfusion, and thereby reduce sympathetic nervous system activity by clearing secretions (14).

Pulmonary function tests are critical for diagnosing and evaluating the severity of various pulmonary diseases. After maximal inspiration, spirometry measures FVC and FEV1 during a rapid and complete exhalation (15). Apart from using Pulmonary Function Tests, we included sputum weight measurement for 5 days pre and post intervention as an important outcome measure of the study. The weight of sputum can be used to evaluate the efficacy of a treatment. Studies have demonstrated that sputum weight could be used to monitor different changes in airway inflammation over the time and evaluate treatment efficacy (16).

We intended to do this research with the thought that this research will shed light on the relative effectiveness of biofeedback Acapella and biofeedback flutter in enhancing pulmonary function in COPD patients. This data could assist respiratory therapists in selecting the most effective biofeedback therapy for their patients. Moreover, this study could stand as a baseline to use biofeedback in various conventional therapeutic practices and find out the effectiveness of the treatment. We also encourage upgrading the airway clearances devices in the best possible way for a better outcome for the patients and the therapists.

MATERIALS AND METHODS

An experimental study was conducted at Father Muller Medical College Hospitals to investigate the efficacy of acapella therapy in reducing sputum weight in patients with COPD. Using a random sample, 30 subjects who met the inclusion criteria were selected, i.e., male and female, aged 40 to 60 years, and grade II or III COPD (GOLD classification). Exclusion criteria included pneumothorax, respiratory failure, angina, pulmonary embolism, active hemoptysis, neurologic deficits, visual disturbances, and uncooperative patients. All the data was collected by using a standardized questionnaire and spirometry. Data was analyzed by the use of descriptive statistics and independent t-tests.

Procedure

Thirty subjects clinically diagnosed with COPD were selected as per the inclusion and exclusion criteria. Brief explanation and written informed consent were obtained. Participants were divided randomly into two groups using the closed envelope method: Biofeedback Acapella and Biofeedback Flutter. Both groups were treated for 15-20 minutes/session/day for a total duration of 5 days. Oxygen saturation was measured with a pulse oximeter at the fingertip as a pretest. The same test was repeated after the intervention to determine post-test results. Group participants were assessed for FEV1 and FVC using a computerized spirometer prior to the start of the study, and the exact measurements were repeated after five days for the post-test. All the individual's sputum weight was analyzed posttest, immediately after the therapy, 1 hr. post therapy session and from post 1 hr. to the next day before the therapy began.

$$W = (W1+W2+W3).$$

W = Total weight of sputum per day

W1= weight of sputum during session

W2 = weight of sputum 1 hr. post session

W3 = weight of sputum 1 hr. post to the next day's therapy session.

The total of sputum was calculated for each day as day1, day2, day3, day4, day5 and the results were analyzed accordingly.

Treatment protocol

Feedback acapella group

The patient should sit in a comfortable and supported position with the elbows resting on the table or the patient half lying down. The mouthpiece should be held firmly in the mouth before and during exhalation. The patient is then asked to inhale deeply and exhale for 3 seconds as far as possible, holding the cheeks firmly while exhaling. The exhalation should last for around 3 - 4 times longer than the inhalation. This is repeated for 10-20 breaths. The patient can then cough "huff" 3 to 4 times to increase secretion.

By connecting a manometer to the Acapella device, the patient can visualize the amount of pressure they are exhaling. This can help to improve the patient's exhalation volume. The device is sterilized after each use using gas sterilization. The devices are sterilized using gas sterilization at the end of each day, except for the manometer.

The resistance knob helps in adjustments of expiratory pressure and oscillatory frequency. The patient should exhale for 3-4 seconds, when the device vibrates. If the patient cannot continue the exhalation for this long, the resistance knob can be adjusted anticlockwise to decrease the resistance of the vibrating orifice, allowing the patient to exhale at a lower flow rate. This will result in the desired ratio of inspiration to expiration of 1:3 - 1:4. As and when the

proper range is achieved, the patient can be asked to exhale at a greater or lesser rate depending on the response they feel to the vibrating pressure.

A manometer was interfaced with the Acapella device via a rubber tube with an extended mouthpiece. The patient was instructed to exhale through the mouthpiece, and the manometer displayed the pressure that he generated.

Feedback flutter group

The patient was instructed to sit in a comfortable upright position with their back straight and their elbows resting on the chair or table. The patient was then asked to tilt their head slightly upward to keep their airway open. The mouthpiece of the device was placed in the patient's mouth and their lips were sealed tightly around it. The patient was then instructed to take a deep breath and hold it for 2 or 3 seconds. They were then asked to exhale into the flutter, while causing the steel ball inside the device to vibrate continuously. This was repeated for 15 exhalations, for a total of three sets of 15 exhalations over 15 to 20 minutes. After every series of exhalations, the patient was asked to "HUFF" and cough to help them cough up any mucus. The pressure gauge on the device deflected as the patient exhaled, allowing them to visualize the exhaled pressure. This improved the patient's forced expiratory volume and served as visual feedback for the device.

The manometer was interfaced with the flutter device via a rubber tube with an extended mouthpiece. The expiratory pressure generated by the patient caused the manometer to deflect, indicating the amount of pressure that the patient was exhaling. The frequency of the oscillations produced by the flutter device can be adjusted by tilting the device up or down from its original horizontal position. The patient can choose an angle that will result in the required transmission of vibrations to the chest wall, which will optimize the mobilization of mucus. The sterilization procedure for the flutter device is the same as for the Acapella device.

Statistical analysis

Data was tabulated and analyzed using both descriptive and inferential statistics. All parameters were evaluated using version 17.0 of the statistical package for social science (SPSS). Paired t-test was used to determine the statistical difference within the groups, whereas the independent t-test (Student t-Test) was used to determine the statistical difference between the groups.

RESULTS

Thirty participants completed the research. The mean ages of the eighteen males and twelve females were 47.10 and 50.20 years, respectively (Table 1).

Table 1: Demographic data

Number of patients (n = 30)	Male	Female
Age (in years)	47.10±9.18	50.20±9.26

The pre-test and post-test values of the biofeedback acapella group and the biofeedback flutter group are presented in Table 2. The analysis revealed statistically significant differences between pretest and posttest within biofeedback acapella group and pretest and post-test within biofeedback flutter group (Table 2). A comparison of the means of biofeedback acapella and biofeedback flutter on FVC shows no significant increase in the post-test mean values and therefore are comparable, but biofeedback acapella performed significantly well within the group. Similarly, biofeedback flutter performed more effectively within its group rather than compared between both the biofeedback acapella and the biofeedback flutter group.

Table 3 compares the mean difference of pre-test and post-test FVC and FEV1 between the biofeedback acapella group and the biofeedback flutter group. The mean difference of FVC in the biofeedback acapella group was 0.22 ± 0.07, with a p-value of 0.528. The mean difference of FEV1 in the biofeedback acapella group was 0.25 ± 0.06, with a p-value of 0.701 (Table 3). These results indicate that there was no significant difference between the biofeedback acapella group and the biofeedback flutter group in terms of their ability to improve FVC and FEV1 in COPD patients. In other words, both devices were equally effective in improving ventilation in COPD patients.

When comparing the means of biofeedback acapella and biofeedback flutter on SPO2, there is again no significant increase in the means after the test. As before, biofeedback acapella shows higher mean of its pre-test and post-test but not much significance when

compared to the pre-test and post-test of the flutter group respectively.

Table 4 presents the values of oxygen saturation assessed every day before and after treatment sessions for both groups as pretest and posttest measures. In comparison of oxygen saturation within the biofeedback acapella group between the days there is a statistically significant results observed with an F value 30.894 and p value less than 0.001. Results of the biofeedback flutter group shows that the comparison between all 5 days significantly increased with the F value 61.530 and p value less than 0.001 (Table 4).

A comparison of the mean values of biofeedback acapella and biofeedback flutter in terms of sputum weight shows a significant increase in sputum expectorated (Table 5). The mean sputum weight of both the biofeedback acapella group and the biofeedback flutter group did not show any statistical difference. It is suggestive that both the airway clearance devices work effectively in reducing sputum weight. Post-test statistical analysis for FVC, FEV1, SPO2, revealed not a high statistically significant difference between both the groups (Table 5).

Similarly, sputum weight of both the groups showed significant improvement in both the groups and no statistical difference between the groups. To determine the total amount of sputum removed per day the values of sputum expectorated during treatment, after one hour, post hour to next day before treatment were observed for both the groups. The total weight of sputum increased in the first 2 days and then deteriorated from the 3rd day in both the groups. Both the groups showed significant difference in pre and posttest, but not a significant difference between each other.

Table 2: Comparison of pre and post-test values of biofeedback acapella group and biofeedback flutter group

Groups	Parameters	Pretest		Post test		t value	p value
		Mean	SEM	Mean	SEM		
Biofeedback Acapella group	FVC(L)	3.02	0.24	3.24	0.23	2.95	0.016*
	FEV1(L)	2.95	0.26	3.20	0.26	3.90	0.002*
Biofeedback Flutter group	FVC(L)	2.41	0.11	2.73	0.15	2.32	0.036**
	FEV1(L)	2.87	0.20	3.08	0.20	2.21	0.044**

Table 3: Comparing mean difference of pre-test and post-test values between biofeedback acapella group and biofeedback flutter group

	GROUP	Mean	SEM	t value	P value
DIFF FVC (litres)	Biofeedback acapella	0.22	0.07	0.639	0.528
	Biofeedback flutter	0.32	0.14		
DIFF FEV1 (litres)	Biofeedback acapella	0.25	0.06	0.387	0.701
	Biofeedback flutter	0.20	0.09		

Table 4: Comparing pre-test and post-test values of oxygen saturation in biofeedback acapella and biofeedback flutter device

Groups	Days	Mean ±SEM		F value	P value
		Pretest	Post test		
Biofeedback acapella	Day 1	91.8 ± 0.5	91.9 ± 0.3	30.894	< 0.001
	Day 2	92.5 ± 0.4	92.6 ± 0.4		
	Day 3	93.1 ± 0.4	93.1 ± 0.4		
	Day 4	93.2 ± 0.3	93.7 ± 0.4		
	Day 5	94.3 ± 0.4	94.8 ± 0.3		
Biofeedback flutter	Day 1	92.1 ± 0.4	92.4 ± 0.3	61.530	< 0.001
	Day 2	92.4 ± 0.3	92.9 ± 0.4		
	Day 3	93.3 ± 0.3	93.8 ± 0.2		
	Day 4	93.8 ± 0.3	94.3 ± 0.2		
	Day 5	94.4 ± 0.2	94.9 ± 0.2		

Table 5: Comparison of sputum weight in grams between biofeedback acapella and biofeedback flutter group

Days	Groups	Mean (grams)	SEM	F value	P value
Day 1	Biofeedback acapella	28.46	1.02	4.025	< 0.001
	Biofeedback flutter	26.28	0.88		
Day 2	Biofeedback acapella	30.02	1.12	4.628	< 0.001
	Biofeedback flutter	28.32	1.03		
Day 3	Biofeedback acapella	28.43	1.18	10.056	< 0.001
	Biofeedback flutter	30.72	1.08		
Day 4	Biofeedback acapella	27.01	0.09	5.258	< 0.001
	Biofeedback flutter	30.10	1.01		
Day 5	Biofeedback acapella	25.66	0.07	3.743	< 0.001
	Biofeedback flutter	29.89	1.00		

SEM (Standard Error of Mean) of sputum weight for the biofeedback acapella group and the biofeedback flutter group on days 1-5. The p-value of <0.0001 for each day indicates a statistically significant difference between the groups. The F and p values were calculated using one-way ANOVA.

DISCUSSION

Positive expiratory pressure devices (PEP) are increasingly used as an alternative to conventional physiotherapy treatments for the respiratory system. They are well-accepted by patients and can be used unsupervised, making them more convenient and easier to follow. However, it is important to consider the pathophysiologic mechanisms of hypersecretory diseases when selecting a PEP device. PEP devices work by creating positive pressure during exhalation, which helps clear mucus from the airways. This is achieved by increasing intrathoracic pressure, which pushes mucus out of the airways and into the larger airways, where it can be coughed up (17). There are several PEP devices, each with their advantages and disadvantages. Some devices, such as the flutter and the acapella, produce high-frequency vibrations that help loosen mucus. Other devices, such as the PEP mask, create positive pressure during exhalation.

The study aimed at comparing the effectiveness of flutter and acapella biofeedback devices on lung function and sputum clearance in patients with COPD. The results were convincing and showed that the Acapella and Flutter devices effectively improved lung function and sputum clearance. There have been studies on the clinical and mechanical evaluation of Flutter and Acapella devices but less on the evaluation

of feedback with positive expiratory pressure devices in terms of mechanical function or use in patients. It was decided to compare the effectiveness of visual feedback with flutter and acapella.

There are several possible explanations for the greater efficacy of Acapella and flutter devices. First, PEP is provided by both acapella and flutter devices, which helps to purge congestion from the airways. This is essential for individuals with COPD and other respiratory diseases that can lead to mucus accumulation (18). Second, both devices are simple to use and versatile in application. This makes them a viable alternative for individuals who are unable or hesitant to use more complex respiratory therapy devices (19). Third, Users are generally tolerant of both devices. Both devices have been demonstrated to be user-friendly, safe, and effective.

Although there are no significant differences in the comparison, yet, biofeedback acapella was slightly more effective than biofeedback flutter, and the therapists suggest that the patient was more comfortable to use biofeedback acapella as it is more versatile to use. Nevertheless, both the devices proved to be effective in expectorating sputum. The devices provided substantial improvement in removing the secretions after each session.

A visual feedback system is known to provide visual feedback. A manometer was used to provide visual feedback with flutter and acapella. By connecting a manometer to positive expiratory pressure devices, the patient can visualize the amount of air exhaled. This improves the patient's forced expiratory volume. The individual capacity of exhalation by feedback-positive expiratory pressure device and expiration time was determined by frequency outcome (20-22).

It provides a similar oscillation frequency within the necessary range to reduce the viscoelastic property of mucus. Thus, the positive expiratory pressure feedback device increases sputum clearance and improves lung function. The feedback device provides better patient understanding and involvement during therapy sessions, which enables effective treatment. This is supported by the study by Rekha *et al.*, (7), which found that biofeedback respiratory therapy devices can improve patient performance and produce robust effects on health and reduce stress.

The results clearly suggest that biofeedback is a more practical and advanced option than the conventional PEP devices for improving lung function in patients with COPD. However, further research work is required to confirm the current results and determine optimal duration and frequency of use of both the PEP devices and there is immense scope in advancing the research and development of respiratory therapy treatment devices. Overall, the results suggest that both acapella and flutter are effective, convenient, and affordable options for improving lung function.

CONCLUSION

This study showed that both acapella device and flutter device are extremely effective in improving lung function, oxygen saturation, and airway clearance in patients with COPD. They are a good alternative to conventional physiotherapy to remove secretions and improve gaseous exchange.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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